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SUN PHARMA

Customer ID : ME1650 M/s. Metapharma (Valpharma)
Order No : 006ESF3612, Qty: 120Kg

CERTIFICATE OF ANALYSIS

PRODUCT	**: PENTOXIFYLLINE EP**		
BATCH No.	**: PNOOXPFL009**	**A. R. No.**	**: MO0280**
MFG. DT.	**: JANUARY 2015**	**RELEASE DATE**	**: 21.01.15**
EXP. DT.	**: DECEMBER 2019**	**PAGE**	**: 01 of 01**

Sr #	TEST	SPECIFICATION	RESULT
1	Description	White or almost white, crystalline powder.	White crystalline powder
2	Solubility	Soluble in water, freely soluble in methylene dichloride, sparingly soluble in Ethanol (96%)	Complies
3	Identification		
	A. Melting Point	Between 103 °C to 107 °C	105.6 °C
	B. IR	The IR absorption spectrum of the sample in KBr dispersion should be concordant with similarly recorded spectrum of Pentoxifylline working standard.	Complies.
	C. Thin layer Chromatography	The Principal spot in chromatogram obtained with test solution is similar in position and size to the principal spot in chromatogram obtained with the reference solution.	Complies.
	D. Reaction of Xanthines	It gives the reaction of Xanthines.	Complies.
4	Appearance of solution	The solution is 'clear' and not more intensely coloured than reference solution Y_7.	Complies.
5	Acidity	Not more than 0.2ml of 0.01M Sodium Hydroxide solution required.	Complies
6	Chloride	Not more than 100 ppm.	Complies
7	Sulphate	Not more than 200 ppm.	Complies
8	Heavy metals	Less than 10 ppm	Complies
9	Loss on drying	Not more than 0.5% w/w	0.19% w/w
10	Sulphated Ash	Not more than 0.1% w/w	0.06%
11	Related substances (by HPLC)		
	Impurity A	Not more than 0.10%	<0.005%*
	Impurity C	Not more than 0.10%	<0.005%*
	Impurity F	Not more than 0.10%	<0.010%*
	Impurity J	Not more than 0.10%	<0.005%*
	Highest unknown impurity	Not more than 0.10%	0.06%
	Total Impurities	Not more than 0.50%	0.10%
12	Assay (By Potentiometric)	99.0% - 101.0% w/w (ODB)	100.0% w/w
13	Residual Solvents		
	a) Methanol	Not more than 1000 ppm	12 ppm
	b) Methylene dichloride	Not more than 500 ppm	Not detected
	c) Toluene	Not more than 890 ppm	Not detected
	d) Dimethylformamide	Not more than 880 ppm	12 ppm
14	Particle size By Malvern	d(0.1) : Not Less than 5.0µm	9.39µm
		d(0.5) : Between 25.0 µm and 42.0 µm	27.38µm
		d(0.9) : Not More than 100 µm	55.39µm
15	Bulk Density** Untapped	0.300-0.490 g/mL	0.30g/mL
	Tapped	0.490-0.750 g/mL	0.58g/mL

(*) Value indicated is "Below Quantification Limit",

REMARKS : The product is **satisfactory** to the prescribed standards of quality in respect of the above mentioned tests as per Ph. Eur 8.0 & Party's** specification.

Note: DATA REPRODUCED FROM ORIGINAL COA.

DATE OF ISSUE OF COA. : 14.02.15

PREPARED BY : **VERIFIED BY :**

DATE : 14.02.15 **DATE :** 14.02.15

Sun Pharmaceutical Ind. Ltd. PANOLI